UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,066	09/20/2001	Hazire Oya Alpar	41577/263691	4735

23370 7590 05/12/2005

JOHN S. PRATT, ESQ
KILPATRICK STOCKTON, LLP
1100 PEACHTREE STREET
ATLANTA, GA 30309

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,066	ALPAR ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *7-10 and 24-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,11-23 and 36-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed March 4, 2005 has been entered. Claims 1-6 and 11-23 have been amended. Claims 7-10 and 24-35 have been withdrawn. Claims 1-6, 11-23 and 36-39 are under consideration in this office action.

2. A complete reply to the FINAL rejection must include cancellation of nonelected or withdrawn claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Withdrawal of Rejections

3. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) The written description rejection of claims 1-6 and 11-23 under 35 U.S.C. 112, first paragraph; and

b) The rejection of claims 1-6 and 11-23 under 35 U.S.C. 112, second paragraph.

Response to Arguments

4. Applicants' arguments filed March 4, 2005 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The rejection of claims **1-2, 4-6, 11-12, 16, 18-19 and 37** under 35 U.S.C. 102(b) as being anticipated by Illum (WO 97/20576) is maintained for reasons already of record.

The rejection was on the grounds that Illum teach a pharmaceutical composition comprising a polycationic carbohydrate or pharmaceutically acceptable derivative thereof, wherein the polycationic carbohydrate comprises a water-soluble alkylated chitosan or a pharmaceutically acceptable salt or derivative thereof or a mixture thereof. Illum also teach compositions comprising chitosan derivatives and pharmaceutical compositions comprising diluents, microparticles, and biologically active agents such as bacterial antigens.

Applicants' assert that Illum fails to teach or suggest a polycationic carbohydrate comprising an alkylated chitosan. However applicants' are reminded that the claims recite alternative language and are not only drawn to compositions wherein the polycationic carbohydrate comprises a water-soluble alkylated chitosan. Rather the claims are also drawn to compositions comprising a pharmaceutically acceptable derivative or compositions comprising a pharmaceutically acceptable salt or compositions comprising derivatives thereof or compositions comprising a mixture thereof.

Moreover, Illum teach that chitosan derivatives include esters, ethers or other derivatives formed by bonding acyl and/or alkyl groups. Illum also states that chitosan and their derivatives are commercially available and it is noted that the teaching of Illum

are not limited to only their examples. It is the examiner's position that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Therefore contrary to applicants' argument, the prior art is relevant for all it discloses and is not limited somewhat inferior uses such as not being suitable to all mucosal sites.

Applicants' assertions that the instant composition has a far wider range of pharmaceutical applications however this argument is not persuasive. In response to applicant's argument a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The rejection of claims 13-15,17 and 20-22 under 35 U.S.C. 103(a) as being unpatentable over Illum in view of Eyles et al., is maintained for reasons already of record. The rejection was on the grounds that it would have been prima facie obvious at the time of applicants' invention to have used the known pharmaceutical compositons as taught by Illum and modify the compositions to include the combination of the V and F1 antigen of *Yersinia pestis* comprised within nanospheres as taught by Eyles et al., because Eyles et al., teach that it is well known in the art to make and use phamaceutical compostions that protect labile vaccines from degradation and enhance adsorption. Illum has been discussed above; therefore applicants' arguments drawn to the alkylated chitosan are still not persuasive.

Applicants' assert that Eyles et al., fail to teach or suggest a polycationic carbohydrate comprising an alkylated chitosan. However applicants' are reminded that the claims recite alternative language and are not only drawn to compositions wherein the polycationic carbohydrate comprises a water-soluble alkylated chitosan but also to compositions comprising a pharmaceutically acceptable derivative or pharmaceutically acceptable salt or derivatives thereof or mixtures thereof.

Applicants' assert that Eyles et al., fail to disclose any adjuvant other than cholera toxin. However, contrary to applicants' assertions, Eyles et al., teach microencapsulation of the V and F1 antigen subunits (page 699). Thereby meeting the limitation drawn to a combination of the V and F1 antigens.

In response to applicants' argument that there is no suggestion to combine the references since Eyles et al., do not specifically recite the use of chitosan, the examiner

recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one would have a reasonable expectation of success since no more than routine skill would have been required to use well known antigens that provide a protective mucosal immune response wherein the antigens can be proteins from any pathogen, as taught by Illum in commerically available microspheres which contain the antigen combination when the art teaches the success and usefulness of using both the protective F1 and V antigens as taught by Eyles et al. Moreover, no more than routine skill would have been required to the modify the well known composition since the modification merely incorporates using equivalent antigenic products and well known microsphere encapsulation for the well known purpose of enhancing mucosal adsorption and inducing immunity in a subject. Therefore applicants' arguments are not persuasive and the rejection is maintained.

7. The rejection of claim 3 under 35 U.S.C. 103(a) as being unpatentable over Illum in view of Kotze et al., is maintained for reasons already of record. The rejection was on the grounds that it would have been prima facie obvious at the time of applicants' invention to have used the known polycationic carboyhdrates as taught by Illum and modify the compositions to include the N-trimethyl chitosan as taught by Kotze et al.

Applicants' argue that the Kotze et al., reference teach away from the claimed invention because it teaches the N-trimethyl chitosan (TMC) is only as effective as chitosan glutamate. However, it is the examiner's position that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims.

Moreover, applicants' argument that the TMC exhibits an increased adjuvant effect is not persuasive, since the instant claims do not become patentable simply because they have been described as somewhat inferior to some other product for the same use. There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.,* 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was

unknown at the time of the prior invention."); *Abbott Labs v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed.Cir.1999). Therefore, applicants' contention that TMC has an increased adjuvant effect is not persuasive since the prior art structure is capable of performing the intended use, thus it meets the claim.

8. The rejection of claims 22, 36 and 38 under 35 U.S.C. 103(a) as being unpatentable over Illum and Eyles et al., and further in view of Kotze et al., is maintained for reasons already of record. The rejection was on the grounds that it would have been prima facie obvious at the time of applicants' invention to have used the known pharmaceutical compostions comprised as nanospheres or cationnic pluronic compounds as taught by Illum and Eyles et al., which are surface modified with chitosan as taught by Kotze et al.

Applicants' assert that none of the references teach that the cationic pluronics are surface modiefed with the polycationic carbohydrate. However, Eyles et al., teach encapsulation within microparticulate copolymeric carriers, such as poly-DL-lactide (PLA) microspheres serves to protect the labile vaccines from degradation and enhance adsorption (page 699). These copolymers meet the limitation of cationic pluronic. Kotze et al., teach that chitosan is also known for its ability to be used as a coating material for multilamellar liposomes (page 1197). Therefore the prior art teach cationic pluronics are surface modiefed with the polycationic carbohydrate.

Applicants' again argues that the Kotze et al., reference teach away from the claimed invention because it teaches the N-trimethyl chitosan (TMC) is only as effective

as chitosan glutamate and does not discuss TMC's increased adjuvant effect. However, the disclosed teachings and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Thus, if the prior art structure is capable of performing the intended use, then it meets the claim. Therefore contrary to applicants' argument, the prior art meets the limitations of the instant claims and the rejection is maintained.

9. The rejection of claim 23 under 35 U.S.C. 103(a) as being unpatentable by Illum (WO 97/20576) in view of Eyles et al., is maintained for reasons already of record. The rejection was on the grounds that it would have been prima facie obvious at the time of applicants invention to have used the known method of producing pharmaceutical compostions as taught by Illum to include encapsulation of the bacterial antigens as taught by Eyles et al.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one would have

a reasonable expectation of success since no more than routine skill would have been required to use a combination of protective antigens comprised within polycationic carbohydrates. Moreover, no more than routine skill would have been required to the modify the well known composition since the modification merely incorporates using encapsulation of antigenic material within microparticulate polymeric carriers to protect labile vaccines from degradation and enhance adsorption. Thus applicants' arguments are not persuasive and the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 38-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to a pharmaceutical vaccine composition for use as an immunostimulant comprising a polycarbohydrate, wherein the polycationic carbohydrate comprises a water-soluble alkylated chitosan or a pharmaceutically acceptable salt or derivative thereof or a mixture thereof; and a first material capable of forming particles,

wherein the pharmaceutical vaccine composition is in the form of particles; and wherein the polycationic carbohydrate is distributed throughout the particles including at the surface.

The claims are so broad that they encompass every type of vaccine which effects all types of diseases, disorders and infections in any type of animal, yet the compositions fail to include an agent which would invoke protective immunity in a subject.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood,* 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.,* 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the

claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Furthermore, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.,* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In *Gostelli,* the Court

determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli,* 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to a pharmaceutical vaccine composition comprising a polycarbohydrate, or a pharmaceutically acceptable salt or derivative thereof or a mixture thereof; and a first material capable of forming particles. The generic statements drawn to the vaccine composition does not provide ample written description for the composition since the claims do not describe a single structural feature which would provide protective immunity to a subject for any type of disease or infection. The specification does provide examples of what qualifies as vaccine compositions. Moreover, the specification only discloses examples limited to sub-unit vaccines such as ones for *Yesinia pestis, Bacillus anthracis*, diptherería toxoid and tetanus toxoid, see page 11, lines 6-19 of the instant specification. As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claims 38-39 are broad generic claims with respect to all the possible infections and disease that this vaccine composition of affect. The possible structural variations are limitless. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack

sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives.

The instant specification fails to provide any experiments that show that such vaccine compositions would be effective in protecting an animal against any type of infection. The term "vaccine" encompasses the ability of the specific antigen to induce protective immunity to a bacterial infection or disease induction. More importantly, there are no challenge experiments to demonstrate that an animal immunized with the claimed vaccine that would be protected from any type infection. There is no disclosure that demonstrates how the vaccine composition would be effective in immunization, nor are their protocols detailing the amount of composition needed to mount a sufficient immune response. There is merely a general outline of vaccines that do not apply directly to the instant invention. Moreover, the specification merely discloses that immune responses were generated in mice, however it is well known that merely generating an immune response does not equate to providing protective immunity. Thus the specification fails to provide an adequate written description of a vaccine composition that will provide protective immunity to all types of infections and diseases.

This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose of preventing any type infection or disease. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced. The specification fails to teach the identity a vaccine with the claimed characteristics. Furthermore, the

specification fails to adequately disclose a description of the claimed vaccines, thus a skilled artisan would be required to de novo locate, identify and characterize the claimed vaccines and biologically active agent with the recited abilities.

Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention. In view of these considerations, a person skilled in the art would not have viewed the teachings of the specification sufficient to show that applicants were in possession of a vaccine composition as claimed. Therefore the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.

New Matter

11. Claims 38-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for a pharmaceutical vaccine composition for use as an immunostimulant comprising a polycarbohydrate, wherein the polycationic carbohydrate comprises a water-soluble alkylated chitosan or a pharmaceutically acceptable salt or derivative thereof or a

mixture thereof; and a first material capable of forming particles, wherein the pharmaceutical vaccine composition is in the form of particles; and wherein the polycationic carbohydrate is distributed throughout the particles including at the surface.

Applicants' did not point to support in the specification for a vaccine composition comprising a polycarbohydrate, or a pharmaceutically acceptable salt or derivative thereof or a mixture thereof; and a first material. There appears to be no teaching of generic vaccine compositions which could treat all infections and diseases. Thus, it appears that the entire specification appears to fail to recite support for the newly recited vaccine composition with the ability to provide protective immunity to infections and/or diseases. Therefore, applicants' must specifically point to page and line number support for a vaccine composition comprising a polycarbohydrate, or a pharmaceutically acceptable salt or derivative thereof or a mixture thereof; and a first material that generates a protective immune response in an animal to which it is administered as recited by the claims. Therefore, the claims incorporate new matter and are accordingly rejected.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
May 5, 2005

LYNETTE R. F. SMITH
SUPERVISORY PATENT
TECHNOLOGY CENTER